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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,991

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Fabrizio Dolfi

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ALEXANDRIA, VA 22314

EXAMINER

KLINKEL, KORTNEY L

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

05/07/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/589,991	Applicant(s) DOLFI ET AL.	
	Examiner Kortney L. Klinkel	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/16/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims

Claims 1-13 are pending in the instant Office action.

Information Disclosure Statement

Acknowledgement is made of applicant's submitting an information disclosure statement on 11/16/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Foreign Priority

Acknowledgement is made of applicant's foreign priority claim to France patent application serial number 0401716 filed 2/20/2004. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Objection to the Title of the Invention

The title of the invention is objected to for the following informalities: The word "Preparing" is misspelled "Porparing". Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation “from the group **comprising** the IL-8RB receptor and the PAC-1 receptor...” (emphasis added). Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. The term “comprising” is an open transitional phrase, meaning that the group following this term is open to members not explicitly recited. See MPEP 2111.03 for more information regarding transitional phrases in claims. Due to the open nature of the transitional phrase used to set forth possible alternative expressions, the metes and bounds of the patent protection sought by the claims are unclear.

Claim 9 and dependent claims 12-13 recite the limitation “said modulator”. Claim 1, upon which these claims ultimately depend, does not make reference to any modulator. The claims lack antecedent basis for the limitation “said modulator”.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-13 are directed to a pharmaceutical composition which comprises a compound that increases the binding of at least one natural ligand to a receptor chosen from the group comprising the IL-8RB receptor and the PAC-1 receptor. With the exception of the compound metronidazole, which has been removed from the possible compound options claimed via proviso, the application does not describe any compounds by structure and/or function which may be capable of increasing the binding of at least one natural ligand to a receptor chosen from the group comprising the IL-8RB receptor and the PAC-1 receptor. Applicant has not demonstrated that they were in full possession of the claimed genus of compounds at the time of the invention. Beginning on page 7, line 14 and continuing through line 34 of the instant specification, Applicant describes steps one could follow to test a compound for modulating activity of at least one receptor chosen from the group comprising the IL-8RB receptor and the PAC-1 receptor. However, the fact remains that the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The fact that any compound both those currently known and currently unknown could be tested does not dispel this rejection, since one of ordinary skill in the art would have no way of knowing whether the compound could or would fall within the scope claimed. Applicant has not provided sufficient details, or relevant identifying characteristics of the desired genus of

compounds sought for patent protection to suggest that applicant was in possession of the claimed invention. Applicant has not provided a structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics to show that the claimed invention is complete. *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613.

The first paragraph of 35 U.S.C. 112 requires that the specification shall contain a written description of the invention. "[T]he essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. *See Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998)." The written description requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). Further, the written description requirement promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term. To satisfy the written

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description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d. Refer also to MPEP 2163 for further details regarding the written description requirement.

In conclusion, a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Leduc et al. (US 5549911).

Leduc et al. disclose pharmaceutical compositions comprising the metronidazole derivative secnidazole (col. 2, lines 57-59, also the formulation of Example 5). Note that talc in example 5 is a filler as per claim 11. Page 6, lines 27-32 states that in addition to metronidazole, derivatives thereof which differ by the substitution, addition or removal of one or more chemical groups are effective in the present invention. As secnidazole

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differs from metronidazole in the substitution of a hydrogen for a methyl on the alcohol tail portion of the molecule, secnidazole would have the required modulating activity required by the instant claims. Regarding claims 4-8 which contains the limitation wherein the composition is for treating at least one stage (1st, 2nd, 3rd, or 4th stage) of rosacea, it is noted that these limitations are recitations of the future intended use of the claimed composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, because the composition of Leduc et al. is identical to that required by the instant claims, it would necessarily be capable of treating at least one stage of rosacea.

Conclusion

Claims 1-13 are rejected. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 10 am to 7 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611